

37 C.F.R. § 1.136(a), and any fees required therefor (including fees for net addition of claims) are hereby authorized to be charged to our Deposit Account No. 19-0036.

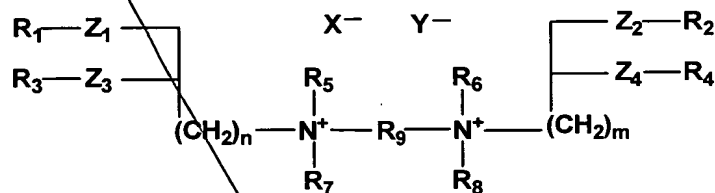
Amendments

In the Claims:

Please cancel claims 1-46 without prejudice or disclaimer.

Please add the following claims:

47. (New) A cationic lipid compound of the following formula



wherein

Z_1, Z_2, Z_3 and Z_4 are the same or different and are $-O-C(O)-$ or $-O-$;

R_1 and R_2 are the same or different and are H, C_1 to C_{24} alkyl or C_1 to C_{24} alkenyl;

R_3 and R_4 are the same or different and are C_1 to C_{24} alkyl or C_1 to C_{24} alkenyl;

R_5, R_6, R_7 and R_8 are the same or different and are H, C_1 to C_{10} alkyl or C_1 to C_{10}

alkenyl;

R_9 is a linker;

n and m are the same or different and are 1 to 8; and

X and Y are the same or different and are non-toxic anions;

provided that R_9 is not C_3 to C_{22} unsubstituted alkyl.

²48. (New) The compound of claim ~~47~~¹, wherein R₉ comprises

- C₁ to C₁₀ substituted alkyl;
- C₁ to C₁₀ alkyloxy;
- C₁ to C₁₀ substituted alkyloxy;
- C₁ to C₁₀ alkenyl;
- C₁ to C₁₀ substituted alkenyl;
- C₁ to C₁₀ alkenyloxy;
- C₁ to C₁₀ substituted alkenyloxy;

^{D'}
² ~~NR₁₀-C(O)-NR₁₁~~^{insert}, wherein R₁₀ and R₁₁ are independently H, C₁ to C₁₀ alkyl, C₁ to C₁₀ substituted alkyl, C₁ to C₁₀ alkenyl, or C₁ to C₁₀ substituted alkenyl;

²
^D ~~NR₁₂-C(O)-NR₁₃-R₁₆-NR₁₄-C(O)-NR₁₅~~^{insert}, wherein R₁₂-R₁₅ are independently H, C₁ to C₁₀ alkyl, substituted C₁ to C₁₀ alkyl, C₁ to C₁₀ alkenyl, or C₁ to C₁₀ substituted alkenyl, and R₁₆ is independently C₁ to C₁₀ alkyl or C₁ to C₁₀ substituted alkyl;

^{D3}
² ~~C(O)-NR₁₇~~^{insert}, wherein R₁₇ is H, C₁ to C₁₀ alkyl, C₁ to C₁₀ substituted alkyl, C₁ to C₁₀ alkenyl, and C₁ to C₁₀ substituted alkenyl;

polyalkyloxy group; amino acid; peptide; saccharide; polypeptide;
polysaccharide; protein; polyamine; peptidomimetic moiety; histone; moiety with DNA binding affinity; or moiety with cell receptor binding affinity.

³49. (New) The compound of claim ~~48~~², wherein R₉ comprises C₁ to C₁₀ substituted alkyl, C₁ to C₁₀ alkenyl or C₁ to C₁₀ substituted alkenyl.

³
⁴50. (New) The compound of claim ~~49~~³, wherein R₉ further comprises a peptide linkage.

⁴
⁵51. (New) The compound of claim ~~50~~⁴, wherein the cationic lipid compound is HB-DMRIE-Ox-Trp-γ-DMRIE.

¹52. (New) The compound according to claim ~~47~~¹, wherein R₉ comprises an optionally substituted polyalkyloxy group.

7 ~~53~~. (New) The compound according to claim ~~52~~⁴⁶, wherein the polalkyloxy group contains from 1 to about 500 alkyloxy mers.

8 ~~54~~. (New) The compound according to claim ~~53~~⁷, wherein the polyalkyloxy group contains from 1 to about 100 alkyloxy mers.

9 ~~55~~. (New) The compound according to claim ~~54~~⁸, wherein the cationic lipid compound is PentaEG-bis-DMRIE.

10 ~~56~~. (New) The compound according to claim ~~55~~⁹, wherein R₉ further comprises a peptide linkage.

Q! 11 ~~57~~. (New) The compound according to claim ~~56~~¹⁰, wherein the cationic lipid compound is PEG34-bis-But-DMRIE-propylamide.

12 ~~58~~. (New) The compound of claim ~~57~~³, wherein the linker comprises a ureyl or bis-ureyl linkage.

13 ~~59~~. (New) The compound of claim ~~58~~⁴, wherein R₉ is a moiety with DNA binding affinity or a moiety with cell receptor binding affinity.

14 ~~60~~. (New) The compound of claim ~~59~~¹³, wherein R₉ is an amino acid, saccharide, peptide, polysaccharide, polypeptide, protein, polyamine, or peptidomimetic moiety.

15 ~~61~~. (New) The compound of claim ~~60~~¹⁴, wherein R₉ is a protein.

16 ~~62~~. (New) The compound of claim ~~61~~¹⁵, wherein said protein is selected from the group consisting of immunoglobulins, ~~transferrin~~^{+transferrins}, asialoglycoproteins, integrins, cytokines, selectins, cell surface receptors, receptor ~~ligand~~^{ligands}, major histocompatibility

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proteins, lysosomotropic proteins, histones, extracellular proteins, protein hormones, growth factors, bacterial exotoxins, low density lipoprotein, alpha-2-macroglobulin, and angiotensin.

¹⁷₆₃. (New) The compound of claim ¹⁶~~62~~, wherein said protein is a transferrin.

¹⁸₆₄. (New) The compound of claim ¹⁶~~62~~, wherein said protein is an immunoglobulin.

¹⁹₆₅. (New) The compound of claim ¹⁶~~62~~, wherein said protein is a histone.

²⁰₆₆. (New) The compound of claim ¹⁴~~60~~, wherein R₉ is a polyamine.

²¹₆₇. (New) The compound of claim ²⁰~~66~~, wherein said polyamine is spermine, spermidine, or a derivative thereof.

²²₆₈. (New) The compound of claim ¹~~47~~, wherein R₉ comprises -R₁₇-NR₁₂-C(O)-NR₁₃-R₁₆-NR₁₄-C(O)-NR₁₅-R₁₈ wherein R₁₂-R₁₅ are independently H, C₁ to C₁₀ alkyl, substituted C₁ to C₁₀ alkyl, C₁ to C₁₀ alkenyl, or C₁ to C₁₀ substituted alkenyl, R₁₆ is independently C₁ to C₁₀ alkyl or C₁ to C₁₀ substituted alkyl, and R₁₇ and R₁₈ are independently optionally substituted C₁ to C₁₀ alkyl or C₁ to C₁₀ alkenyl.

²³₆₉. (New) The compound of claim ²²~~68~~, wherein the cationic lipid compound is SBDU-DMRIE, SBGU-DMRIE, or SHGU-DMRIE.

²⁴₇₀. (New) A composition comprising ^{the} a compound of claim ¹~~47~~, and one or more co-lipids.

D
~~25~~ ^{the} 71. (New) A composition comprising a compound of claim ~~51~~⁵ and one or more co-lipids.

D
~~26~~ ^{the} 72. (New) A composition comprising a compound of claim ~~55~~⁹ and one or more co-lipids.

D
~~27~~ ^{the} 73. (New) A composition comprising a compound of claim ~~57~~¹¹ and one or more co-lipids.

D
~~28~~ ^{the} 74. (New) A composition of comprising a compound of claim ~~68~~²² and one or more co-lipids.

DA
D
~~29~~ ^{the} 75. (New) A composition comprising a compound of claim ~~69~~²³ and one or more co-lipids.

~~30~~ 76. (New) An immunogenic composition comprising an immunogen and a compound of claim ~~47~~.

~~31~~ ³⁰ 77. (New) The immunogenic composition of claim ~~76~~³⁰, wherein said immunogen is an immunogen-encoding polynucleotide.

~~32~~ ³⁰ 78. (New) The immunogenic composition of claim ~~76~~³⁰ further comprising one or more co-lipids.

SUB
CS
~~33~~ 79. (New) A method for inducing an immune response in a vertebrate, said method comprising administering to the vertebrate an immunogenic composition of claim 76 in an amount sufficient to generate an immune response to the encoded immunogen.

~~34~~ ³³ 80. (New) The method of claim ~~79~~³³, wherein the vertebrate is a mammal.

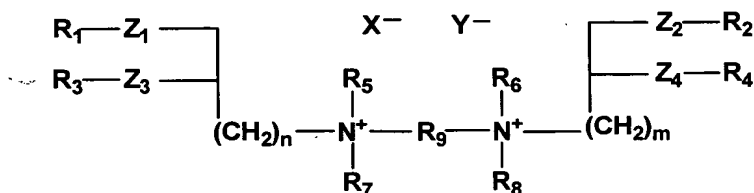
35 ~~81.~~ (New) The method of claim ~~80~~³⁴, wherein the mammal is a human.

82. (New) A method for delivering a biologically active agent to a cell of a plant or animal, said method comprising:

contacting said cell with a lipid aggregate, said lipid aggregate comprising said biologically active agent and a compound of claim 47.

37 ~~83.~~ (New) A pharmaceutical kit for use in delivering a polynucleotide ^{polynucleotide} to a vertebrate, said kit comprising:

a cationic compound of the formula



wherein

Z_1, Z_2, Z_3 and Z_4 are the same or different and are $-O-C(O)-$ or $-O-$;

R_1 and R_2 are the same or different and are H, C_1 to C_{24} alkyl or C_1 to C_{24} alkenyl;

R_3 and R_4 are the same or different and are C_1 to C_{24} alkyl or C_1 to C_{24} alkenyl;

R_5, R_6, R_7 and R_8 are the same or different and are H, C_1 to C_{10} alkyl or C_1 to C_{10} alkenyl;

R_9 is a linker, wherein said linker comprises

C_1 to C_{10} substituted alkyl;

C_1 to C_{10} alkyloxy;

C_1 to C_{10} substituted alkyloxy;

C_1 to C_{10} alkenyl;

C_1 to C_{10} substituted alkenyl;

C_1 to C_{10} alkenyloxy;

C_1 to C_{10} substituted alkenyloxy;

^{D1}
~~NR₁₀-C(O)-NR₁₁~~, wherein R₁₀ and R₁₁ are independently H, C₁ to C₁₀ alkyl, C₁ to C₁₀ substituted alkyl, C₁ to C₁₀ alkenyl, or C₁ to C₁₀ substituted alkenyl;
^{insert}

^{D2}
~~NR₁₂-C(O)-NR₁₃-R₁₆-NR₁₄-C(O)-NR₁₅~~, wherein R₁₂-R₁₆ are independently H, C₁ to C₁₀ alkyl, substituted C₁ to C₁₀ alkyl, C₁ to C₁₀ alkenyl, or C₁ to C₁₀ substituted alkenyl, and R₁₇ is independently C₁ to C₁₀ alkyl or C₁ to C₁₀ substituted alkyl;
^{insert}

^{D3}
~~C(O)-NR₁₇~~, wherein R₁₇ is H, C₁ to C₁₀ alkyl, C₁ to C₁₀ substituted alkyl, C₁ to C₁₀ alkenyl, and C₁ to C₁₀ substituted alkenyl;
^{insert}

polyalkyloxy group; amino acid; peptide; saccharide; polypeptide;
polysaccharide; protein; polyamine; peptidomimetic moiety; histone; moiety with DNA binding affinity; or moiety with cell receptor binding affinity;

n and m are the same or different and are 1 to 8; and

X and Y are the same or different and are non-toxic anions.;

optionally co-lipid;

optionally a polynucleotide;

one or more containers, wherein said cationic compound, said optional co-lipid, and said optional polynucleotide are in the same or different said one or more containers; and

optionally means for administering to a vertebrate said cationic compound, said optional co-lipid, and said optional polynucleotide.

³⁸
~~38~~ (New) The pharmaceutical kit according to claim ~~83~~, wherein said kit further comprises a polynucleotide, wherein said ~~polynucleotide~~ operably encodes a polypeptide within vertebrate cells *in vivo*.

³⁹
~~39~~ (New) The pharmaceutical kit according to claim ~~84~~, wherein said kit contains 1 ng to 30 mg of said polynucleotide.

⁴⁰
~~40~~ (New) The pharmaceutical kit according to claim ~~85~~, wherein said kit contains about 100 ng to about 10 mg of said polynucleotide.

³⁷
~~41~~ ~~87~~. (New) The pharmaceutical kit according to claim ~~83~~, wherein R₉ comprises an optionally substituted polyalkyloxy group.

⁴¹
~~42~~ ~~88~~. (New) The pharmaceutical kit according to claim ~~87~~, wherein said polyalkyloxy group contains from 1 to about 500 alkyloxy mers.

⁴²
~~43~~ ~~89~~. (New) The pharmaceutical kit according to claim ~~88~~, wherein said cationic lipid compound is PentaEG-bis-DMRIE.

⁴²
~~44~~ ~~90~~. (New) The pharmaceutical kit according to claim ~~88~~, wherein R₉ further comprises a peptide linkage.

⁴⁴
~~45~~ ~~91~~. (New) The pharmaceutical kit according to claim ~~90~~, wherein said cationic lipid compound is PEG34-bis-But-DMRIE-propylamide.

³⁷
~~46~~ ~~92~~. (New) The pharmaceutical kit according to claim ~~83~~, wherein said cationic lipid compound is HB-DMRIE-Ox-Trp-γ-DMRIE.

³⁷
~~47~~ ~~93~~. (New) The pharmaceutical kit according to claim ~~83~~, wherein R₉ comprises a bis-ureyl linkage.

⁴⁷
~~48~~ ~~94~~. (New) The pharmaceutical kit according to claim ~~93~~, wherein said cationic lipid compound is SBDU-DMRIE, SBGU-DMRIE or SHGU-DMRIE.